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Reply dated 15 February 2005
Responsive to Final Office Action mailed on 17 December 2004

REMARKS

Claim Rejections Under 35 U.S.C. § 102

Claims 1 through 7, 10 through 16, 19, and 20 were again rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No. 5,291,181 to DePonte.

These rejections are hereby respectfully traversed on the ground that it was not shown in the Office Action that the cited reference teaches every element of any of the rejected claims.

Lack of Anticipation

Each of the three independent **Claims 1, 10, and 19** was amended in the previous Reply to read that the fever indicator provides the signal only when the urine is present. In combination with the original limitations, the effect of this amendment is that these claims convey that the fever indicator provides a signal only when two conditions are met simultaneously, namely only when:

- urine expelled from the wearer's body is present and
- the fever indicator determines from that urine that the wearer's body temperature is above a predetermined threshold value.

It is noted that as originally worded, the independent claims already inherently contained the now explicitly recited limitation that the fever indicator provides the signal only when the urine is present, due to the recitation that the fever indicator determines the body temperature from the urine, which limitation logically requires that the urine be present. Nevertheless, in the interest of expediting the prosecution of the Application, the independent claims were amended in the previous Reply to explicitly recite the previously inherent limitation.

In direct contrast, as noted in the previous reply, the cited DePonte reference clearly discloses that its alarm is activated by the detection of a body temperature at or above a predetermined activating temperature even in a dry condition, *i.e.*, even when no urine is present. There is no indication in the disclosure that DePonte contemplated providing his fever alarm only when urine was present. Instead, there is explicit disclosure that his fever alarm is provided in a dry condition. See column 6 lines 24 through 42.

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As noted in the previous Reply, this difference reveals an advantage of the present invention over the disclosure of the DePonte reference. As clearly explained in the paragraph beginning on page 5 at line 3 of the present Application, the present invention will not provide false alarms by responding to high temperatures while in a dry condition, such as might be encountered inside an automobile on a hot sunny day. On the other hand, the DePonte reference reveals no recognition of such a potential problem and instead includes an alarm that is activated by a high temperature, regardless of whether the condition is wet or dry.

“Optional” Feature in DePonte Reference

In the previous Office Action, the temperature-sensing system of DePonte was explicitly referenced as fulfilling more than one of the limitations of the original claims. In response, the independent claims were amended as noted above and the distinction discussed above was explained. However, in the Final Office Action, that response was deemed to be non-persuasive on the basis that the temperature-sensing system disclosed in the DePonte reference is “an *optional* feature” and “is an additional optional element and not necessary for the function of the primary monitoring system”, the latter reference being to “a monitoring system that is activated by the presence of a quantity of liquid” (Final Action, page 2). In addition, it was stated in the Final Office Action that “[a]lthough DePonte additionally discloses an *optional* feature, which includes a sensor capable of sensing and monitoring high temperatures, the sensor monitoring high temperatures in a dry condition is an additional optional element and not necessary for the function of the primary monitoring system” (Final Action, pages 4 and 5).

The statements characterizing DePonte’s disclosure are accurate, but they are not dispositive of the present issue because, although DePonte discloses the temperature-sensing system as an optional feature of his invention, it is not optional with respect to the rejections of the claims of the present invention. In fact, without the temperature-sensing system, there is no basis in the DePonte reference for the rejections in the previous Office Action or for maintaining those rejections in the Final Office Action. This fact is self-evident in light of the explicit recitation of temperature-sensing limitations in the independent claims of the present invention.

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Thus, as a fundamental point with respect to the rejections of the claims, DePonte's temperature-sensing system must either be included in each rejection or it must be excluded, *i.e.*, either the temperature-sensing system is "out", or it is "in". If it is "out", then none of the limitations of the present claims that relate to temperature-sensing are anticipated by the DePonte reference. If it is "in", then at least the limitations regarding the requirement that urine be present are not anticipated in light of the fact that the alarm in DePonte's temperature-sensing system is activated by the detection of a body temperature at or above a predetermined activating temperature even in a dry condition, *i.e.*, even when no urine is present. It is respectfully averred that it is not proper to take a circular approach of first rejecting the claims on the basis that DePonte discloses a temperature-sensing system and then later dismissing amendments and arguments on the contradictory and mutually exclusive basis that the temperature-sensing system is "optional".

The relevance of two other statements in the Final Office Action is not understood. Apparently in reference to the rejected claims of the present invention, it was stated on pages 2 and 5 that "[t]he comprising language used in the independent claims is inclusive or open-ended and does not exclude additional unrecited elements, compositional components, or steps". This is an accurate statement of the meaning of the term "comprising" and of the effect of its usage in the present claims. However, the relevant issue is not the meaning or the effect of this term, but rather what is explicitly recited in the present claims and therefore must be disclosed in a reference in order for that reference to anticipate these claims. In order for a reference to anticipate the present claims, that reference must disclose a fever indicator that provides a signal only when urine expelled from the wearer's body is present and the fever indicator determines from that urine that the wearer's body temperature is above a predetermined threshold value. The DePonte reference fails to disclose such a device and so fails to anticipate any of the present claims.

Disposable Article versus Durable Article

Additionally, the following point in this section of the Office Action bears comment. In the previous Reply, it was pointed out that Claim 10 explicitly recites that the claimed article is disposable, in contrast to the explicit description in the cited reference that its bed pad is durable.

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In the Final Office Action, this response was deemed to be non-persuasive on the basis that "the article of DePonte is capable of being discarded after one use or several uses" (Final Action, page 2) and "the article is capable of being discarded after one use, thus the article is considered disposable as broadly as claimed" (Final Action, page 4). It is respectfully averred that this re-definition is unwarranted and improper because it ignores both the definition of the term "disposable" that is provided in the present specification, the dictionary definition of the term "disposable", and the common usage of the term "disposable".

The meaning of the term "disposable" is explicitly defined on page 2 at lines 27 through 30 of the specification as originally filed, where the following definition is provided.

The term "disposable" is used herein to describe absorbent articles that generally are not intended to be laundered or otherwise restored or reused as absorbent articles (i.e., they are intended to be discarded after a single use and, preferably, to be recycled, composted or otherwise discarded in an environmentally compatible manner).

The definition that is quoted above from the present specification is consistent with the following dictionary definitions of "disposable". It is particularly noted that precisely the type of article that is presently claimed is recited as exemplifying a disposable article in the following definitions.

- "designed to be used once and then thrown away <disposable diapers>" (Merriam-Webster® Online Dictionary);
- "Designed to be disposed of after use: *disposable diapers*; *disposable razors*" (The American Heritage® Dictionary of the English Language: Fourth Edition. 2000);
- "describes an item that is intended to be thrown away after use: *disposable nappies* [diapers] *a disposable camera*" (Cambridge Advanced Learner's Dictionary).

In contrast, DePonte clearly characterizes his article as durable, rather than disposable, as evidenced by the explicit disclosure that his "monitoring system...is durable and easily cleaned for reuse (column 3, lines 16-17), that his bed pad has "a durable outer surface...for an increased useful life" (column 5, lines 56-57), that his sensor pad "is sponged clean with soap and water, and then with a germicide, for reuse" (column 6, lines 6-7), and that his bed pad "is cleaned

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through conventional machine laundering” (column 6, lines 7-8). In fact, DePonte’s description is completely *inconsistent* with the definitions of the term “disposable” that are quoted above, but is perfectly consistent with the following definitions of the term “durable”.

- “designed to be durable <*durable goods*>” (Merriam-Webster® Online Dictionary);
- “Capable of withstanding wear and tear or decay: *a durable fabric*. (The American Heritage® Dictionary of the English Language: Fourth Edition. 2000);
- “Not depleted or consumed by use: *durable goods*” (The American Heritage® Dictionary of the English Language: Fourth Edition. 2000);
- “A manufactured product, such as an automobile or a household appliance, that can be used over a relatively long period without being depleted or consumed” (The American Heritage® Dictionary of the English Language: Fourth Edition. 2000);
- “able to last a long time without becoming damaged: *The machines have to be made of durable materials*” (Cambridge Advanced Learner’s Dictionary).

Furthermore, the characterization in the Final Office Action of anything that is “capable of being discarded after one use” as being “disposable” defies common usage of the term. For example, even an automobile or an airplane is “capable of being discarded after one use”, but this certainly does not place either of them in the category of “disposable” items. As another example on a less expensive level, a stainless steel fork is “capable of being discarded after one use”, but this certainly does not place it in the category of “disposable” tableware along with cheap plastic forks. Instead, automobiles and airplanes and stainless steel forks are commonly considered to be durable goods. On the other hand, items for which renewal or restoration would be impractical or economically unjustified are commonly considered to be disposable. For example, the removal of ketchup from a paper napkin might somehow be feasible, but only at a much greater expenditure of cost and effort than would be required to simply replace the napkin, so a paper napkin is considered to be disposable. On the other hand, a linen napkin can be washed in water without disintegrating and would be relatively expensive to replace, so it is not considered to be disposable. Throwing away DePonte’s article with its electrical circuit and other durable elements after a single use would not make it “disposable” any more than recycling the fibers from a disintegrated paper napkin would make that napkin “durable” in nature. Thus, the mere statement that something is “capable of being discarded after one use” is not sufficient to

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overcome the well-known meaning and usage of the term "disposable" as contrasted to "durable". In fact, such a simplistic approach would lead to the absurd conclusion that the Great Pyramids of Egypt are "disposable" items, since they were apparently used only once, at least only once for their intended purpose, and then were left in the desert.

In summary with regard to these rejections, the cited DePonte reference fails to teach every element of any of the rejected claims and therefore fails to anticipate any of those claims. Accordingly, it is respectfully requested that the rejections of Claims 1 through 7, 10 through 16, 19, and 20 under 35 USC § 102(b) be reconsidered and withdrawn.

Claim Rejections Under 35 U.S.C. § 103

Claims 9 and 18 were again rejected under 35 USC § 103(a) as being unpatentable over the same DePonte reference in view of U.S. Patent No. 6,541,517 to Murphy *et al.*

These rejections are hereby respectfully traversed on the ground that the requirements of MPEP 2143 for the establishment of a *prima facie* case of obviousness have not been met with respect to either of the rejected claims.

Lack of Teaching or Suggestion of All Claim Elements

As noted above, the DePonte reference fails to teach or suggest all of the limitations of independent Claims 1 and 10, from which Claims 9 and 18 respectively depend. The Murphy *et al.* reference likewise fails to teach or suggest any of the missing limitations and thus fails to remedy the shortcomings of the DePonte reference.

In addition, it is noted that the DePonte reference is directed to an electrical system for monitoring the temperature of a person and to another electrical system for detecting when that person urinates into a pad while, on the other hand, the Murphy *et al.* reference is directed to a method for the treatment of skin disorders through the application of a topical skin care composition that may contain the pharmaceutical compound known as *triacetin* in its formulation. It was not explained in the previous Office Action how a pharmaceutical compound could be incorporated into the invention of DePonte, as proposed in the rejection, and this lack

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was pointed out in the previous Reply. In the Final Office Action, it was stated that “pharmaceuticals providing skin-conditioning benefits are widely used in diaper [*sic*], bed pads, and incontinent garments and are generally topically applied to the absorbent article in manufacture...the motivation for combining the references is to provide the absorbent article of DePonte with a compound that would treat or prevent skin disorders”.

Thus, it appears that the proposal is to apply the pharmaceutical composition of Murphy *et al.* topically onto the bed pad of DePonte, given the fact that only the bed pad 12 is disclosed to contact the skin of the patient (column 5, lines 51-56), while the sensor pad 20 is disclosed to be inserted into the pocket 14 in the bed pad 12 (column 4, lines 54-56; Figure 1) and is thereby isolated from the skin during use (column 5, lines 51 through column 6, line 12). More specifically, in order to meet the stated objective of being provided in a form “that would treat or prevent skin disorders”, the pharmaceutical composition of Murphy *et al.* would have to be applied onto the skin-facing surface of the top layer 70 of the bed pad 12, since the top layer 70 is the layer that contacts the skin. If so, it is noted that such a combination of the references would still fail to contain all of the elements of the rejected claims.

In particular, the proposed combination would not contain all of the elements of either **Claim 9** or **Claim 18** because these claims contain a common limitation that the fever indicator comprises the plasticizer. If the pharmaceutical composition were applied topically to the skin-facing surface of the top layer of the bed pad, the pharmaceutical composition would clearly not even be in contact with the electrical alarm circuit (fever indicator), in light of the disposition of the alarm circuit (fever indicator) inside the pocket of the bed pad. In fact, given that the alarm circuit (fever indicator) is “mounted” to the sensor pad and the sensor pad is fitted into the pocket 14 that is in the “bottom surface” of the bed pad 12 (column 4, lines 54-57), the alarm circuit (fever indicator) is actually separated from the top layer 70 by the absorbent middle layer 60 (column 5, lines 51-57). Clearly, an element that is separated by two structural layers from another element cannot “comprise” that other element. Thus, in the proposed combination of the references, the alarm circuit (fever indicator) could not possibly comprise the pharmaceutical composition that is applied onto the skin-facing surface of the top layer of the bed pad.

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Furthermore, the proposed combination would not contain all of the elements of **Claim 9** because this claim contains the limitations that the wearable article comprises an outer cover and the fever indicator is affixed to the outer cover. According to the statements of rejection in both Office Actions, in the article of DePonte, the structural equivalent of the outer cover is the waterproof bottom layer 50 of the bed pad 12. However, the fever indicator (alarm circuit 22) is not affixed to the bottom layer 50 (outer cover) as in **Claim 9**, but instead is "mounted" to the sensor pad 20, as is explicitly described in the DePonte reference (column 4, lines 55-57), and this sensor pad is fitted inside the pocket, apparently in an orientation such that the alarm circuit faces toward the absorbent middle layer 60, *i.e.*, faces away from the outer cover (bottom layer 50), as indicated by Figure 1 and the description of the passage of liquid in the paragraph beginning in column 5 at line 51. The fact that the alarm circuit (fever indicator) is not affixed to the outer cover (bottom layer) is also self-evident from the fact that the sensor pad onto which the alarm circuit (fever indicator) is mounted can be inserted into and removed from the pocket, one wall of which is apparently formed by the bottom layer. If the alarm circuit (fever indicator) were affixed to the outer cover (bottom layer), it would have to be detached in order to be removed, but instead it apparently simply "comes out" as a part of the sensor pad 20.

Triacetin as a Pharmaceutical Plasticizer

Examination of the Murphy *et al.* reference reveals that "triacetin" and "plasticizer" appear together in only one sentence in the paragraph beginning in column 4 at line 40 of the reference. Specifically, it is disclosed in this sentence that "[t]riacetin has been used as a pharmaceutical plasticizer". It is respectfully noted that the DePonte reference does not disclose a pharmaceutical compound, much less a pharmaceutical compound in which triacetin could be incorporated as a plasticizer. Thus, the modification proposed in the Office Action of incorporating a pharmaceutical plasticizer into an article that does not comprise a pharmaceutical compound is clearly not suggested or motivated by any disclosure found in the cited references.

Furthermore, the disclosure of Murphy *et al.* does not indicate that triacetin is used as a plasticizer. Instead, triacetin is the active ingredient in the pharmaceutical composition. Thus, the application of this pharmaceutical composition onto the top layer of DePonte's bed pad would not constitute an incorporation of triacetin as a plasticizer, and therefore the claim

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limitation regarding comprising a plasticizer would not be met. By way of analogy, one material from which bolts can be made is steel, but the incorporation of steel in plate form into a structure does not constitute an incorporation of bolts into that structure.

Antifungal Usefulness of Triacetin

It is also respectfully noted that the statement in the Office Actions that "Murphy discloses the use of plasticizers for the benefit of an anti-fungal property" at column 4, line 46 is a selective mischaracterization of the disclosure. First, Murphy does not disclose that plasticizers, in general, are useful as antifungal agents. In addition, in the same paragraph, beginning at line 59, it is disclosed that "despite disclosure that triacetin is a general antifungal agent, a U.S. Food & Drug Administration Over-the-Counter (OTC) Drug Review Panel has concluded that there is no evidence that triacetin is effective in any fungal disease other than the soggy toeweb form of athlete's foot". Such a specifically limited anti-fungal property would not be useful in DePonte's bed pad, which he discloses is to be worn elsewhere than on the foot. Therefore, the motivation alleged in the Office Actions for the incorporation of a plasticizer to obtain the benefit of an antifungal property is not provided by the references, themselves.

In summary, the cited prior art references, either singly or in combination, fail to teach or suggest all of the limitations of the rejected claims. The references similarly fail to provide any suggestion or motivation to modify their teachings. Furthermore, the modification proposed in the Office Action would be technically impractical.

Thus, none of the three requirements of MPEP 2143 for the establishment of a *prima facie* case of obviousness has been met with respect to either of the rejected claims. Accordingly, it is respectfully requested that the rejections of Claims 9 and 18 under 35 USC § 103(a) be reconsidered and withdrawn.

In light of the above remarks, it is respectfully requested that the rejections be reconsidered and withdrawn and that the pending claims be allowed. An Advisory Action is also respectfully requested in response to this Reply.

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